UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,657	03/20/2001	Margaret Ann Johns	5947-01-DRK	4802

7590 04/29/2004

David R Kurlandsky
Warner Lambert Company
2800 Plymouth Road
Ann Arbor, MI 48105

EXAMINER	
GUCKER, STEPHEN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,657	JOHNS ET AL.	
	Examiner	Art Unit	
	Stephen Gucker	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *8-14 and 17-34* is/are withdrawn from consideration.

5)☒ Claim(s) *2,3,5-7 and 35* is/are allowed.

6)☒ Claim(s) *1,4,15 and 16* is/are rejected.

7)☒ Claim(s) *36* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.

3. New claim 36 (misnumbered as claim 35) is objected to under 37 CFR 1.75 as being a substantial duplicate of new claim 35 (misnumbered as claim 34). When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The grounds of this objection could be obviated by amending claim 35 to unequivocally indicate that it is a closed claim, which could be done by amending the claim to read:

--An isolated and purified DNA sequence consisting of a sequence which encodes a polypeptide of SEQ ID NO:5.--

4. Claims 1, 4 and 15-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In order for claims drawn to percentage sequence identity of a recited sequence to meet the written description

requirement, the disclosure must provide adequate examples or guidance by which the artisan would be able to make a reasonable determination of what regions of the sequence could be substituted, added to, or deleted, yet still provide a sequence that retains the biological properties envisioned by the specification. This can be done by providing multiple examples of sequence identity between different species forms of the encoding sequence (e.g. human, rat, mouse, bovine, etc.) and indicating conserved regions between species which provides guidance to the artisan as to which regions of the sequence should remain the same and which regions could be altered. Alternately, the disclosure could teach what are the critical regions of the encoding sequence that provide critical amino acid residues that are important in forming active sites, glycosylation regions, disulfide binding providing secondary or tertiary structure, ion pores or channels, ligand or ion binding sites, transmembrane regions, etc. The instant disclosure fails to adequately describe different species forms and conserved regions of the instant invention. Nor does the instant disclosure teach functionally important amino acid residues or polypeptide fragments of the encoded protein so that the artisan has guidance as to which encoding nucleotides can be changed and which kept the same in order to encode a functional calcium channel subunit. The specification does mention on page 6 that the instant invention shares a conserved domain with vonWillebrand factor A3 domain. However, this domain has been described in a large number of proteins involved in the mediation of cell adhesion, and not with ion channel function, which is what the instant invention is drawn to. While the instant invention and the encoding sequence for vonWillebrand factor A3 domain may share an evolutionary

ancestor from which the homology between the sequences may arise, it does not appear that this conserved domain provides sufficient guidance for the instant claims to recite a percentage of sequence identity because the biological functions between the vonWillebrand factor A3 domain (cell adhesion) and the instant invention (calcium channel function) have significantly diverged over the course of evolution, and the significance of this conserved domain in regards to ion channel function is completely unestablished to the point where it cannot be said that this domain should remain constant in order to have a reasonable expectation of producing a functional ion channel because said domain has not been associated with ion channel function, but with cell adhesion function. Likewise, the splice variants described on page 6 of the specification also do not provide guidance as to important domains for ion channel function because the splice variants appear to be drawn to soluble proteins, and a soluble protein cannot function as an ion channel because ion channels require a hydrophobic component in order to traverse the cell membrane. Indeed, a secreted soluble protein by definition is not a transmembrane protein which is required for ion channel function. Without an adequate written description, the disclosure as filed does not place the claimed genus of sequences sharing a percentage sequence identity with SEQ ID NO:3 while retaining the desired and recited biological function of a calcium channel subunit into the hands of the public.

However, the examiner would like to note that claim 2 provides an allowable genus by reciting a product-by-process type of claim by using hybridization language which is adequately described and enabled by the instant specification, and the

Examiner invites Applicant to file an amendment canceling claims 1 and 4 and amending dependent claim 7 to also depend on claim 2, or to submit a new dependent claim to recombinant host cells that would be dependent on claim 2 in order to maximize the breadth of Applicant's patent protection should the instant application proceed to issue.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

6. Claim 15 is rejected under 35 U.S.C. 102(a) as being anticipated by Myers. Myers discloses Primer A and Primer B and the amplification conditions used to generate GenBank Accession number G36524 (December 31, 1997), which is described as a human Homo sapiens sequence tagged site (STS) cDNA. The DNA amplification methods used by Myers (initial incubation, denaturation, annealing, polymerization, PCR cycles, etc.) fall within the scope of the instant claim because the amplification primers used comprise at least 8 consecutive nucleotides of SEQ ID NO:3 (Primer B by itself comprises nucleotides 3537-3546 of SEQ ID NO:3 and nucleotides 3712-3720 of SEQ ID NO:3). The amplification product obtained comprises 224 nucleotides of SEQ ID NO:3 (nucleotides 3537-3760 of SEQ ID NO:3). See the attached sequence comparison at the end of this Office Action.

7. Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Soares et al. ("Soares"). Soares discloses a 328 base pair nucleotide sequence which is an express

sequence tag (EST, GenBank Accession Number AA815447) with one mismatch that shares 99.7% identity with nucleotides 1579-1907 of instant SEQ ID NO:3 and was put in the public domain on February 13,1998. Soares et al. does not explicitly disclose a kit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a kit containing the nucleotide sequence of Soares for the ease and convenience of having a probe or primer for a voltage-gated calcium channel alpha2/delta subunit as disclosed by Soares because of the need to use the probe or primer to identify tissues containing this voltage-gated calcium channel alpha2/delta subunit for pharmacological screening assays to search for new anti-convulsant drugs that could block this channel. See the attached sequence comparison at the end of this Office Action.

8. Claims 2-3, 5-7, and 35 are in condition for allowance.

9. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-

0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone number for this Group is currently (703) 872-9306.

SG

Stephen Gucker

April 26, 2004

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600